

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Goode, Jr. et al.
Appl. No.	: 10/633,329
Filed	: August 1, 2003
For	: SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA
Examiner	: Nasser, Robert L.
Group Art Unit	: 3735

DECLARATION OF APURV KAMATH

Dear Sir:

I, Apurv Kamath, declare as follows:

1. I am a citizen of the United States, residing at 4072 Meade Ave., San Diego, CA 92116, and believe that I am the original, first and joint inventor with Paul V. Goode, Jr. and James H. Brauker of the subject matter which is claimed and for which a patent is sought on the invention entitled "SYSTEMS AND METHODS FOR PROCESSING ANALYTE SENSOR DATA", the specification of which was filed on August 1, 2003 as U.S. Appl. No. 10/633,329.

2. I have read the Office Action mailed February 4, 2008 and reviewed the cited references, and understand that pending Claims 1-10, 12, 14, 17-31, 33, 36-48, 50, 52, 55-57, 59, 61-67, 73-82 and 93-110 have been rejected as obvious in view of U.S. Patent Publication No. 2002/0161283 to Shin et al. ("Shin") in view of the Mastrototaro article entitled "The Minimed Continuous Glucose Monitoring System" ("Mastrototaro") and U.S. Patent No. 6,558,320 to Causey, III et al. ("Causey").

3. I and my co-inventors have developed systems and methods for evaluating a quality of a calibration of an analyte sensor using statistical and/or clinical data analysis methods conventionally performed only on retrospective data sets. The implementation of the statistical and/or clinical data analysis methods for prospective data processing has required more than routine experimentation.

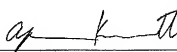
4. In response to the Examiner's assertion that "it would have been obvious to modify the Shin/Mastrototaro combination to calibrate in real time, as it is merely the

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substitution of one equivalent calibration technique for another," it is my expert opinion that the implementation of the retrospective evaluation of Mastrototaro in real time would require more than routine experimentation for one skilled in the art. Retrospective statistical analysis is designed to analyze a data (e.g., a point and/or series of points) at any particular time within the data set, wherein the analysis of the data takes into account information available in the "future" (for example, whether the sensor's sensitivity has "drifted" over time (before, during and/or after the data being analyzed)). Mastrototaro requires at least three meter-sensor data pairs for each day, which data pairs are used to determine a meaningful correlation coefficient for sensor data measured during the entire day (including data points obtained prior to the at least three meter-sensor data pairs). Mastrototaro teaches that a meaningful correlation coefficient cannot be calculated when there are fewer than three meter-sensor data pairs for a day, which implies that a real time implementation of the evaluation of Mastrototaro would not allow for a meaningful correlation coefficient to be calculated until at least three meter-sensor data pairs are obtained on any given day, which may not occur until later in a day or not at all in some circumstances (for example, the commercial Dexcom continuous glucose sensor currently requires that only two reference blood glucose readings per day are input into the system). Accordingly, because a prospective (real-time) implementation of a conventionally statistical and/or clinical data analysis method cannot take into account what will happen in the future, additional considerations must be included in the implementation of the prospective algorithm, which are beyond routine experimentation, to ensure that the statistical and/or clinical data analysis that takes into account only information available *prior* to the data point being analyzed, will be adequately predictive such that it is useful in data processing (e.g., sensor calibration) for data going *forward in time*.

5. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true. I declare that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 2/21/08



Apurv Kamath